

Please type a plus sign (+) inside this box

+

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	09/584,936
Filing Date	31 May 2000
First Named Inventor	Michael G. Kahn
Group Art Unit	3626
Examiner Name	Kalinowski, Alexander G.
Attorney Docket Number	FSTK 1000-0

Sheet 1 of 4

U.S. PATENT DOCUMENTS

Examiner Initials [*]	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
<i>AK</i>	A2	4,992,939		Tyler	02-12-1991	
	A3	5,148,366		Buchanan et al.	09-15-1992	
	A4	5,181,162		Smith et al.	01-19-1993	
	A5	5,222,236		Potash et al.	06-22-1993	
	A6	5,267,155		Buchanan et al.	11-30-1993	
	A7	5,272,623		Grubb et al.	12-21-1993	
	A8	5,369,763		Biles	11-29-1994	
	A9	5,553,216		Yoshioka et al.	09-03-1996	
	A10	5,655,130		Dodge et al.	08-05-1997	
	A11	5,657,255		Fink et al.	08-12-1997	
	A12	5,734,883		Umen et al.	03-31-1998	
	A13	5,774,887		Wolff et al.	06-30-1998	
	A14	5,963,967		Umen et al.	10-05-1999	
<i>AK</i>	A15	6,205,455		Umen et al.	03-20-2001	
	A16	6,505,218		Umen et al.	01-07-2003	
	A17					
	A18					
	A19					
	A20					

FOREIGN PATENT DOCUMENTS

Examiner Initials [*]	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
<i>AK</i>	B1		WO9963473		Phase Forward Inc.	12-09-1999		
	B2		WO9849647		Medical Science	11-05-1998		
	B3		EP 1244024		Systems	09-25-2002		
	B4		EP 0832462		Michael Umen & Co.	08-28-2002		
	B5		WO9634348		Michael Umen & Co.	10-31-1996		
<i>AK</i>	B6		CA2150765		Michael Umen & Co.	07-25-2000		
	B7				Vulpe, Michel			
	B8							
	B9							
	B10							

Examiner
Signature

Alexander G. Kalinowski

Date
Considered

4/2/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box ☐

PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

Complete if Known

Application Number	09/584,936
Filing Date	31 May 2000
First Named Inventor	Michael G. Kahn
Group Art Unit	3626
Examiner Name	Kalinowski, Alexander G.
Attorney Docket Number	FSTK 1000-0

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>ML</i>	C25	"Documentum Market Application Profile" (advertisement), Documentum, Inc. (no date).	
	C26	Manell, Per, "Pharmaceutical Document Management" (presentation slides), PharmaSoft AB, Feb. 12-15, 1995.	
	C27	Marr, Andrew P., "SGML – The Business Perspective" (presentation slides) Glaxo Research & Development Ltd., Feb. 12-15, 1995.	
	C28	Schmuff, Norman R., "The Standards – Based CMC CANDIA Project – Background" (presentation slides), Food and Drug Administration, Feb. 14-15, 1994.	
	C29	Hampshire, N., "dbPublisher," EXE 4(4) (Sep. 1989) pp. 24 et. seq.	
	C30	"Black and Veatch selects Documentum as corporate document management standard; largest U.S. engineering and design firm implements Documentum to increase competitive advantage in worldwide market," Business Wire, p. 12061100, Dec. 6 1994.	
	C31	Walter, M., "Documentum: open approach to automating workflow and management of long documents," Seybold Report on Publishing Systems 23(7), p. 3(11), Dec. 1, 1993.	
	C32	Pallatto, J., "Software design tool gets new module," PC Week 5(41) (Oct. 10, 1988) 24.	
	C33	SCHETTINI, S., et al., "SGML is Here to Stay," Publish. 9(6) (Jun. 1994) 71-78.	
	C34	DYSON, E., "SFQL: When Structure Counts," Release 1.0 91(4) (Apr. 1991) 14(5).	
<i>ML</i>	C35	"SGML Primer" What Every Software Company Should Know about SGML," Release 1.0, 91(7) (Jul. 1991) 7(7).	

Examiner
Signature

Alexander G. Kalinowski

Date
Considered

4/1/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box ☐

PTO/SB/08B (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 4

Complete if Known

Application Number	09/584,936
Filing Date	31 May 2000
First Named Inventor	Michael G. Kahn
Group Art Unit	3626
Examiner Name	Kalinowski, Alexander G.
Attorney Docket Number	FSTK 1000-0

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
<i>AK</i>	C36	"Accurate Information & Ontos," Release 1.0, 91(7) (Jul 1991) 23(2).
	C37	Seymour, J., "Forms Software: Next Hot Category," PC Magazine 7(16) (Sep. 1988) 77(2).
	C38	BRENESAL, B., "Q&A 4.0: the tradition continues," PC Sources 2(10) (Oct. 1991) 361.
	C39	KITNEY, R.I. et al., "Clinical trials of an electronic medical record system," Computers in Cardiology, Cleveland, OH, Sep. 13-16, 1998, IEEE, 201-204.
	C40	FRIDSMA, DOUGLAS B., et al. "Representing Medical Protocols for Organizational Simulation: An Information Processing Approach" J. Computational & Mathematical Org. Theory 4(1): 71-95 (1998)
	C41	SILKER, BERT, "Guide to Clinical Trials" Chapter 2 pp. 7-9; Chapter 3 pp. 10-14; Chapter 4 pp. 15-20; Chapter 5 pp. 21-26; Chapter 12 pp. 78-84; Chapter 68 pp. 482-489; Chapter 122 pp. 953-960 (1991)
	C42	KUHN & ROUGHTON, "Now Securing Every Row", Oracle Magazine, July/August 2003, available at http://otn.oracle.com/oramag/oracle/03-jul/043security.html ; visited 8/7/2003.
	C43	Domain Pharma, "Clintrial 4" - Setting Up Clintrial, Release 4.2, 1999, pp. 1-478
	C44	Domain Pharma, "Clintrial 4" - Working with Review, Release 4.2, 1999, pp. 1-532
	C45	Domain Pharma, "Clintrial 4" - Entering, Editing and Retrieving Data, Release 4.2, 1999, pp. 1-366
<i>AK</i>	C46	Domain Pharma, "Clintrial 4" - Managing Data, Release 4.2, 1999, pp. 1-352

Examiner
Signature

Alexander G. Kalinowski

Date
Considered

4/2/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box



PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 4

Complete if Known

Application Number	09/584,936
Filing Date	31 May 2000
First Named Inventor	Michael G. Kahn
Group Art Unit	3626
Examiner Name	Kalinowski, Alexander G.
Attorney Docket Number	FSTK 1000-0

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>AK</i>	C47	Domain Pharma, "Clintrial 4", Working with Multisite, Release 4.2, 1999, pp. 1-204	
	C48	Domain Pharma, "Clintrial 4", Reference Guide, Release 4.2, 1999, pp. 1-380	
	C49	Domain Pharma, Clintrial Database Schema, Version 4.2, Modified: 11/06/1998	
	C50	Matoren, Gary M., "The Clinical Research Process in the Pharmaceutical Industry", New York: Marcel Dekker, Inc., especially but not exclusively Chapters 8, 9 and 11, (1984)	
	C51	Centerwatch.com, "Glossary", available http://www.centerwatch.com/patient/glossary.html (visited 12/8/2003).	
<i>AK</i>	C52	FDA, Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, ICH, (April 1996).	

RECEIVED
JAN 06 2004
GROUP 3600

Examiner
Signature

Alexander G. Kalinowski

Date
Considered

11/2/01

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.